

EXHIBIT D
PENDING CLAIMS
AS OF SEPTEMBER 26, 2002

IN U.S. APPLICATION SERIAL NO. 09/724,396
ATTORNEY DOCKET NO. 10271-007

73. A sustained release formulation comprising palivizumab or one or more fragments thereof that immunospecifically bind to one or more RSV antigens.
74. A pharmaceutical composition adapted for pulmonary delivery comprising palivizumab or one or more fragments thereof that immunospecifically bind to one or more RSV antigens and a suitable carrier.
85. A method of preventing a RSV infection in a mammal, said method comprising administering to said mammal a prophylactically effective amount of the sustained release formulation of claim 73.
86. A method of treating or ameliorating one or more symptoms associated with a RSV infection in a mammal with a RSV infection, said method comprising administering to said mammal a therapeutically effective amount of the sustained release formulation of claim 73.
87. A method of preventing a RSV infection in a mammal, said method comprising administering to the lungs of said mammal a prophylactically effective amount of the pharmaceutical composition of claim 74.
88. A method of treating or ameliorating one or more symptoms associated with a RSV infection in a mammal with a RSV infection, said method comprising administering to the lungs of said mammal a therapeutically effective amount of the pharmaceutical composition of claim 74.
180. A method of preventing a RSV infection in a mammal, said method comprising administering to the lungs of said mammal a first dose of a prophylactically effective

amount of a composition comprising palivizumab or one or more fragments thereof that immunospecifically bind to one or more RSV antigens, wherein said prophylactically effective amount results in a prophylactically effective concentration of at least 20 ng per mg of lung protein at least 20 days after the administration of said first dose and prior to the administration of a subsequent dose.

181. A method of treating or ameliorating one or more symptoms associated with a RSV infection in a mammal infected with RSV, said method comprising administering to the lungs of said mammal a first dose of a therapeutically effective amount of a composition comprising palivizumab or one or more fragments thereof that immunospecifically bind to one or more RSV antigens, wherein said therapeutically effective amount results in a therapeutically effective concentration of at least 20 ng per mg of lung protein at least 20 days after the administration of said first dose and prior to the administration of a subsequent dose.

186. The method of claim 180 or 181, wherein said palivizumab or antibody fragments thereof are administered by a nebulizer or inhaler.

187. The method of claim 180 or 181, wherein said palivizumab or antibody fragments thereof are administered intramuscularly, intravenously or subcutaneously.

189. The method of claim 180 or 181, wherein the mammal is a human subject, a human subject which has had a bone marrow transplant, an elderly human subject, or a human subject which has cystic fibrosis, bronchopulmonary dysplasia, congenital heart disease, congenital immunodeficiency or acquired immunodeficiency.

190. The method of claim 180 or 181, wherein the mammal is a human infant.

191. The method of claim 180 or 181, wherein the mammal is a human infant born prematurely or is at risk of hospitalization for a RSV infection.

200. A method of preventing RSV infection in a human subject, comprising administering to said subject a first dose of a prophylactically effective amount of

palivizumab or one or more fragments thereof that immunospecifically bind to one or more RSV antigens, wherein said prophylactically effective amount is a dose of less than 15 mg/kg of said palivizumab or fragments, and wherein said administration results in a prophylactically effective serum titer of said palivizumab or fragments that is at least 75 µg/ml at least 20 days after the administration of said first dose and prior to the administration of a subsequent dose.

201. A method of treating or ameliorating one or more symptoms associated with RSV infection in a human subject with a RSV infection, comprising administering to said subject a first dose of a therapeutically effective amount of palivizumab or one or more fragments thereof that immunospecifically bind to one or more RSV antigens, wherein said therapeutically effective amount is a dose of less than 15 mg/kg of said palivizumab or fragments, and wherein said administration results in a therapeutically effective serum titer of said palivizumab or fragments that is at least 75 µg/ml at least 20 days after the administration of said first dose and prior to the administration of a subsequent dose.

202. The method of claim 200, wherein said prophylactically effective serum titer is at least 75 µg/ml at least 30 days after the administration of said first dose and prior to the administration of a subsequent dose.

203. The method of claim 201, wherein said therapeutically effective serum titer is at least 75 µg/ml at least 30 days after the administration of said first dose and prior to the administration of a subsequent dose.

204. The method of claim 200 or 201, wherein the serum titer is at least 100 µg/ml.

205. The method of claim 200 or 201, wherein the serum titer is at least 125 µg/ml.

206. The method of claim 200 or 201, wherein the serum titer is at least 150 µg/ml.

207. A method of preventing RSV infection in a human subject, comprising administering to said subject a first dose of a prophylactically effective amount of palivizumab or one or more fragments thereof that immunospecifically bind to one or more

RSV antigens, wherein said prophylactically effective amount is a dose of less than 10 mg/kg of said palivizumab or fragments, and wherein said administration results in a prophylactically effective serum titer of said palivizumab or fragments that is at least 40 µg/ml at least 20 days after the administration of said first dose and prior to the administration of a subsequent dose.

208. A method of treating or ameliorating one or more symptoms associated with RSV infection in a human subject with a RSV infection, comprising administering to said subject a first dose of a therapeutically effective amount of palivizumab or one or more fragments thereof that immunospecifically bind to one or more RSV antigens, wherein said therapeutically effective amount is a dose of less than 10 mg/kg of said palivizumab or fragments, and wherein said administration results in a therapeutically effective serum titer of said palivizumab or fragments that is at least 40 µg/ml at least 20 days after the administration of said first dose and prior to the administration of a subsequent dose.

209. The method of claim 207, wherein said prophylactically effective serum titer is at least 40 µg/ml at least 30 days after the administration of said first dose and prior to the administration of a subsequent dose.

210. The method of claim 208, wherein said therapeutically effective serum titer is at least 40 µg/ml at least 30 days after the administration of said first dose and prior to the administration of a subsequent dose.

211. The method of claim 207 or 208, wherein the serum titer is at least 50 µg/ml.

212. The method of claim 207 or 208, wherein the serum titer is at least 80 µg/ml.

213. The method of claim 207 or 208, wherein the serum titer is at least 100 µg/ml.

214. A method of preventing RSV infection in a human subject, comprising administering to said subject a first dose of a prophylactically effective amount of palivizumab or fragments thereof that immunospecifically bind to one or more RSV antigens, wherein said prophylactically effective amount is a dose of less than 5 mg/kg of

said palivizumab or antibody fragments, and wherein said administration results in a prophylactically effective serum titer of said palivizumab or fragments that is at least 20 µg/ml at least 20 days after the administration of said first dose and prior to the administration of a subsequent dose.

215. A method of treating or ameliorating one or more symptoms associated with RSV infection in a human subject with a RSV infection, comprising administering to said subject a first dose of a therapeutically effective amount of palivizumab or fragments thereof that immunospecifically bind to one or more RSV antigens, wherein said therapeutically effective amount is a dose of less than 5 mg/kg of said palivizumab or fragments, and wherein said administration results in a therapeutically effective serum titer of said palivizumab or fragments that is at least 20 µg/ml at least 20 days after the administration of said first dose and prior to the administration of a subsequent dose.

216. The method of claim 214, wherein said prophylactically effective serum titer is at least 20 µg/ml at least 30 days after the administration of said first dose and prior to the administration of a subsequent dose.

217. The method of claim 215, wherein said therapeutically effective serum titer is at least 20 µg/ml at least 30 days after the administration of said first dose and prior to the administration of a subsequent dose.

218. The method of claim 215 or 216, wherein the serum titer is at least 30 µg/ml.

219. The method of claim 215 or 216, wherein the serum titer is at least 40 µg/ml.

220. The method of claim 215 or 216, wherein the serum titer is at least 80 µg/ml.

221. The method of claim 200, 201, 207, 208, 215 or 216, wherein the dose is 3 mg/kg or less.

222. The method of claim 200, 201, 207, 208, 215 or 216, wherein the dose is 1.5 mg/kg or less.

223. The method of claim 200, 201, 207, 208, 215 or 216, wherein the dose is 1 mg/kg or less.
224. The method of claim 200, 201, 207, 208, 215 or 216, wherein said palivizumab or fragments are administered by a nebulizer or inhaler.
225. The method of claim 200, 201, 207, 208, 215 or 216, wherein said palivizumab or fragments are administered intramuscularly, intravenously or subcutaneously.
226. The method of claim 200, 201, 207, 208, 215 or 216, wherein said subject is a human subject which has had a bone marrow transplant, an elderly human subject, or a human subject which has cystic fibrosis, bronchopulmonary dysplasia, congenital heart disease, congenital immunodeficiency or acquired immunodeficiency.
227. The method of claim 200, 201, 207, 208, 215 or 216, wherein said subject is a human infant.
228. The method of claim 227, wherein said subject is a human infant born prematurely or is at risk of hospitalization for a RSV infection.
229. The method of claim 200, 201, 207, 208, 215 or 216, wherein said palivizumab or fragments are administered 1, 2, 3, 4, or 5 times during the RSV season.
230. The method of claim 200, 201, 207, 208, 215, or 216, wherein said palivizumab or fragments are administered in a sustained release formulation.